

## REMARKS

In accordance with the above amendments, claims 26-41 have been canceled, without prejudice, and new claims 42-58 substituted for them. Claims 42-58 remain under consideration in this application and no claim has been allowed.

It is believed that the new slate of claims overcomes each of the rejections lodged with regard to the canceled claims which they replace. The present claims include modifications directed to clarify and better define the steps of the method in accordance with the invention. Certain suggestions made by the Examiner in the Action have been found to be well taken and have been incorporated in the newly-written claims.

With respect to the rejection of the claims on the merits, it is first noted that canceled claims 26-31 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al (U.S. Patent 5 195 969, filed April 26, 1991), in view of Levy (U.S. Patent 4 490 421). Although applicant believes his invention to be patentably distinct from this combination, it is believed that the Wang et al reference indeed is not of good date with respect to the rejected claims. In this regard, applicant respectfully traverses the Examiner's assertion that none of the claims in this application are fully supported by the disclosure of the parent application.

The present application is not a continuation-in-part, but a divisional application of Serial No. 07/727,664, filed July 9, 1991, now U.S. Patent 5 270 086, issued December 14, 1993 which, in

turn, is a continuation-in-part of Serial No. 07/411,649, filed September 25, 1989. It is submitted that the present claims 42-44, and 50-52, including both independent claims (42, 50), are fully supported by the original disclosure. In this regard, a review of the application as originally filed reveals that each of the steps of the independent claims and additional limitations of the dependent claims are clearly set forth. For example, the co-extrusion step, step (a) in the independent claims are set forth in the text on pages 4 and 5, especially page 5, lines 4-11; also, the multilayer, co-extruded material is illustrated in Figure 4. Figure 1, of course, illustrates all the steps claimed and the further steps (b)-(d) (claim 42) and (b)-(e) (claim 50) are discussed in the summary, page 2, line 28-page 3, line 2; and generally on pages 5 and 6, as are the proposed bonding methods of claims 43, 44, 50 and 51.

The only details missing from the original specification involve cataloging the specific names of certain materials which are enumerated under the auspices of the broader concept of the originally filed specification. Applicant, therefore, believes that the Wang et al reference should be withdrawn and not applied with respect to these claims (i.e., 42-44, 50-53). It is further noted that the Wang et al reference is not relevant to the material added in the continuation-in-part application as it does not mention the enumerated materials. This means that with respect to the steps of the method to which Wang et al is relevant, it is not of good date and so should not be applicable even to claims which

did not exist in the application prior to the filing of the continuation-in-part.

Prior claims 26-31 were also rejected under 35 U.S.C. § 103 as being unpatentable over Levy (U.S. Patent 4 490 421) in view of Dyke (U.S. Patent 4 003 382), Parker, ("Co-Extruded Composite Film") and either Japanese reference JA53-45353 or Wiggins et al (U.S. Patent 3 707 590). Levy does teach a polymeric balloon having a rather high burst pressure of at least 200 psi and a radial expansion beyond its nominal inflated diameter of less than 5% at 200 psi. That balloon may be drawn and expanded in a blow molding operation. His preferred material is PET.

The 35 U.S.C. § 103 rejections contained in items 8 and 9 of the Examiner's Action involve a multiplicity of references (minimum of four) which are suggested in a particular combination which is difficult to follow even with hindsight, let alone prospectively based on the teachings of the references themselves, as is required for any combination to be valid. With respect to item No. 8, claims 26-31 were rejected under 35 U.S.C. § 103 as unpatentable over Levy (U.S. Patent 4 490 421) in view of Dyke (U.S. Patent 4 003 382), Parker ("Co-Extruded Composite Film", Modern Plastics Encyclopedia, 1973-74) and either Japanese reference JA53-43535 or Wiggins et al (U.S. Patent 3 707 590).

According to the Examiner, it would have been obvious to co-extrude the plastic material described by Levy (a single layer PET high-pressure balloon) with heat sealable plastic material to form a double layer before heating, drawing and expanding the tube,

drawing the tube and radially expanding the tube because (a) Levy teaches conventional catheter balloon fabricating techniques, (b) Dyke suggests providing a double layer balloon to provide an inner heat sealable layer together with an outer lay, (c) Parker suggests co-extruding a low melting point plastic with a high melting point plastic in order to form a double layer tube which has good sealing properties and is virtually free from pinholes and (d) either (i) the Japanese reference or (ii) teach extruding different plastic materials to form a tube which is thereafter expanded to fit an oriented material. Applicant respectfully traverses.

The Levy reference discloses a catheter balloon having low expansion, rather high burst strength  $\geq 200$ , psi consisting of a single-layer biaxially oriented material (preferably PET) which is formed by heating, drawing and expansion into a mold or retaining means of the desired size. Levy does not disclose any details or reveal any possible problems one might have in attaching the balloon to a catheter. Levy fails to disclose any reason whatever for modifying the single layer into a two-layer balloon system let alone suggest modifications in the manner suggested. The Dyke references teach sealing polyurethane balloon member utilizing attached thermoplastic polyurethane bands. Dyke clearly does not suggest the use of diverse compositions in a two-layer system. The Parker reference contains a brief overview including general comments with regard to co-extruded composite films and does suggest that physical properties may be varied by co-extruding

different materials. The fact the multiple layers may prevent pinholes from lining up, while interesting, has no significance with respect to the claimed invention and would only be significant assuming both layer materials were prone to pinholes. The article is quite general and teaches no specifics with regard to the present invention.

Wiggins et al teach a combination of various laminations for diverse purposes as in producing roll-laminated pre-labeled saran. One of the purposes of the lamination is to allow saran to be heat sealed at a lower temperature. This reference, however, has application in a diverse art totally unrelated to the production of catheter balloons and it is far from clear that the multilayer structure of Wiggins et al would be in any manner compatible with the process for making the multilayer structure of the present invention.

Of course, in determining the propriety of the rejection under 35 U.S.C. § 103, it is well settled that the obviousness of the invention cannot be established by combining the teachings of the prior art absent some teaching, suggestion or incentive supporting the combination. See, for example, In re Fine, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988). Also, the burden for establishing a prima facie case of obviousness is upon the Examiner and the burden can only be satisfied by showing objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led such individual to combine the relevant teachings of the references. The rejection based on § 103

must rest on a factual basis with the facts being interpreted without hindsight reconstruction of the invention from the prior art. The Examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See In re Warner, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967).

It is believed that only through hindsight could one possibly construct the combination suggested. There is nothing in Levy to suggest that any modifications are needed for his high strength balloon and, although co-extrusion is known from the art, the art fails to suggest that the multilayer technology will work in the particular process and successfully produce the properties desired between the inner and outer layers in a catheter balloon produced by the claimed process. Furthermore, a reference such as Wiggins et al is deemed to be directed to a diverse subject using different laminating techniques which do not adapt to the claimed process. It is believed that only by picking and choosing through hindsight that one could reach a conclusion of obviousness with respect to the present claims.

The application of the combination as above and further in view of Merrill (U.S. patent 4 055 682) and Lambert (U.S. Patent 4 666 437) with respect to previous claims 32-41 under 35 U.S.C. § 103 in item 9 is also respectfully traversed. It is believed that the rejection should not stand in the first place based on the reason given with respect to the rejection of former claims 26-31. Also, the additional references which deal with applying

hydrophilic coating to plastic materials to reduce the coefficient of friction when the materials are wet are not presently being claimed as new per se but only in light of the limitations of the process which, it is believed, more fundamentally distinguish over the previously-discussed combination. Furthermore, the additional references do not teach the adaptability of the polymer coatings with regard to thin film inflatable members such as a balloon catheter.

In view of the above amendments taken together with the remarks contained herein, applicant believes his present claims to be patentably distinct from any combination of the applicable art and respectfully requests reconsideration and early allowance of them.

Respectfully submitted,

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